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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/840,795	04/23/2001	Erin E. Murphy	SF0818KQ	5250

28008 7590 06/21/2004

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EXAMINER	
O HARA, EILEEN B	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 06/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/840,795	MURPHY ET AL.	
	Examiner	Art Unit	
	Eileen O'Hara	1646	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 12 May 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☐ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *11-15,21 and 22*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER

Continuation of 5. does NOT place the application in condition for allowance because: The declaration under 37 CFR 1.132 filed April 28, 2003 and resubmitted May 12, 2004 is insufficient to overcome the rejection of claims 11-15, 21 and 22 based upon lack of utility under 35 U.S.C. 101, and therefore the rejection under 102(e), as set forth in the previous Office actions because: although the data attached to the declaration demonstrate that the mRNA encoding the protein of SEQ ID NO: 17 is increased in a lung idiopathic pulmonary fibrosis model and in a lung macaque Ascaris challenge model, this does not provide information on the activity or function of the protein, and does not supply a utility for the protein or antibody to the protein. Applicants' arguments that the specification specifically identifies a utility that is supported by the data and the declaration, in that that the RANK-like protein (RANKL) is involved in the regulation and development of lymphocytes, and thus diseases associated with lymphocyte regulation and development, has been considered but not found persuasive. Although the RANKL receptor of the claimed invention has structural similarity to the TNF family of receptors, simply finding that its transcript is elevated in inflammation does not provide information on how the protein is actually functioning. Although it may be associated with inflammation somehow, there is no information how it is involved - causing inflammation, or resulting from inflammation, and it is not predictable what any activity the receptor has. The Li paper submitted as Exhibit B demonstrates that the Taqman analysis is a very sensitive method used to quantitate interleukin-1β upregulation in ischemia. However, the accuracy of the quantitation of the transcript is not the issue, the issue is that although up-regulated, how is the RANKL protein functioning. Additionally, Li analyzed a known inflammatory cytokine to see if it was involved in ischemic brain tolerance; Li did not determine that the interleukin-1β was an inflammatory cytokine based upon its up-regulation, and also states that though elevated, it may have a potential role in ischemic brain tolerance. Applicants arguments that a cytokine (receptor?) does not have to be expressed at a high level to definitively alter and influence the microenvironment or even the entire organ system in which it is expressed, has been considered but not found persuasive. Even if the receptor were up-regulated correspondingly with the transcript in these disease models, this does not provide one of ordinary skill in the art information on how the receptor is involved in these disease models, as discussed above. Therefore, the rejections are maintained. .